

K964065

NOV - 6 1996

ATTACHMENT 2

510(k) SUMMARY FOR N/T PROTEIN CONTROL SL

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacture	Behringwerke AG Postfach 1140 35001 Marburg Germany
Distributor	Behring Diagnostics Inc. 151 University Avenue Westwood, MA 02090 617-320-3000
Contact Person:	Laura LeBarron
Date of Preparation:	October 9, 1996

2. Device Name/ Classification:

N/T Protein Control SL:	quality control material
Classification Number:	class I (862.1660)

3. Identification of the legally marketed device:

N/T Protein Control SY

4. Proposed Device Description:

The proposed control, N/T Protein Control SL is a control prepared from human serum (liquid) with stabilizers and preservative. It is intended to be used together with the Behring Nephelometer systems (Behring Nephelometer K860894, Behring Nephelometer 100 K892223 and the Behring Nephelometer II K943997) and with the TurbiTimeSystem™ as accuracy and precision controls for the following tests:

IgG
IgA
IgM
C3c
C4
Transferin

Ceruloplasmin
RbP
Ig/L-chain, Kappa
Ig/L-chain, Lambda
IgG 1
IgG 2

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Albumin	IgG 3
α 1-antitrypsin (α 1-proteinase inhibitor)	IgG 4
α 2-macroglobulin	β 2-microglobulin
Haptoglobin	Ferritin
α 1-acid glycoprotein	IgE
Pre-albumin (transthyretin)	

5. Proposed Device Intended Use:

N/T Protein Control SL is intended to be used as accuracy and precision controls in the determination of human serum proteins.

6. Medical device to which equivalence is claimed and comparison information.

N/T Protein Control SL is substantially equivalent in intended use to the N/T Protein Control SY. Both controls are *in vitro* diagnostic reagents intended for use as multi-constituent accuracy and precision controls in the determination of human serum proteins. The N/T Protein Control SY, like the proposed product, is a control in a blood based matrix. Also, both controls are used for accuracy and precision control in immunology assays.

The N/T Protein Control SL differs from the N/T Protein Control SY in that the N/T Protein Control SY is a lyophilized standard while the N/T Protein Control SL is a liquid control.

7. Proposed Device Performance Characteristics:

Precision and reproducibility:

Precision studies using one lot of N/T Protein Control SL were run on the Behring Nephelometer system and on the TurboTimeSystem™. The percent CV's ranged from 0.6 to 8.2 % on the Behring Nephelometer system and from 1.6 to 6.1 % on the TurboTimeSystem™.

Stability

Stability was run according to in-house protocols and the control was found to be stable for at least 12 months at +2 to +8°C, as originally packaged and for at least 15 days at +2 to +8°C, once opened.